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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,646	01/13/2004	Tracee Eidenschink	S63.2B-11321-US01	3946

23552 7590 12/21/2006

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EXAMINER	
SEVERSON, RYAN J	
ART UNIT	PAPER NUMBER
3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/21/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/757,646	EIDENSCHINK ET AL.	
	Examiner	Art Unit	
	Ryan Severson	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) *10-14,16-20 and 39-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,15 and 21-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 May 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/04, 4/04, 7/04, 9/04, 3/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1 (claims 1-46) and catheter assembly 1 (figures 3-5) and sheath embodiment 1 (figures 1, 2, and 10) in the reply filed on 15 November 2006 is acknowledged. The traversal is on the ground(s) that the sheath shown in figure 10 should be combined with the sheath embodiment of figures 1 and 2. This is found persuasive. Figure 10 will now be considered part of sheath embodiment 1 and be included with figures 1 and 2.

2. Catheter assembly 1 previously encompassed figure 10, and therefore the figure is simply being included in the sheath embodiment species, and not changing the nature of the election requirement. Therefore, the requirement is still deemed proper and is made FINAL.

3. Applicant has asserted that claims 16-18 are included in the elected species. However, it is the examiner's position that claims 16-18 encompass only the non-elected sheath embodiment shown in Figures 14 and 15. The limitation in claim 16 stating the "thickness of the sheath defines a guidewire lumen" is clearly shown by reference numeral 106 in figures 14 and 15 with "first and second lumen openings" shown by reference numerals 155 and 157 in the same figures. This feature is not present in the elected species of figures 1, 2, and 10. Therefore, claims 16-18 are withdrawn from further consideration as being drawn to a nonelected species, even though applicant has stated these claims read on the elected species.

4. Claims 10-14, 16-20, and 39-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 15 November 2006.

Information Disclosure Statement

5. The information disclosure statement filed 22 March 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it contains a patent which has a different inventor than that supplied by the applicant (see page 2 of 8) and therefore it is unclear whether the applicant intended the patent number listed to be the citation or another document number by the author listed.

6. The information disclosure statement filed 02 September 2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it contains a patent application publication with an invalid number. All patent application publication numbers have 7 digits following the publication year, and the listed document contains 8 digits.

Drawings

7. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 204 (Figure 5), 500 (Figure 13a), and 502 (Figure 13b). Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any

amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

Claim 32 contains the trademark/trade name TECOPHILIC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a material that the sheath is made from and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1, 5-6, 15, 33, 35, and 37-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone et al. (5,843,027).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). The inner diameters of the first and second portions are different, as they lie coaxially. The sheath is capable of being rotated about the catheter is it is not secured thereron.

9. Regarding claim 5, the sheath can comprise 3 portions (see Column 5, Lines 32-35). The second portion, interpreted in this case to be the second layer (42) of the sheath, would lie on the outside of the first layer (44) but inside a third layer, which is not pictured. Therefore, the second layer lies between the first and third layers.

10. Regarding claim 6, the inner diameter of the second portion of the sheath remains constant along the length of the sheath (see Figure 2).

11. Regarding claim 15, the catheter assembly of Stone et al. reference further includes a stent (28) disposed about the sheath (see Column 6, Lines 51-57 and Column 7, Lines 49-54). The stent has a plurality of stent members defining cell openings (see Figure 1).

12. Regarding claim 33, the sheath of Stone et al. is constructed of a first material and a second material. The inner and outer layers (44 and 42, respectively) can be made from different materials (see Column 5, Lines 51-53 and Lines 65-67).

13. Regarding claim 35, the first material (42) of Stone et al. reference is a polymer matrix and the second material (44) is a reinforcing material. The material of the inner layer of Stone et al. reference is inelastic (see Column 5, Lines 65-66) and therefore interpreted to be reinforcing material.

14. Regarding claim 37, the reinforcing material of Stone et al. reference can be PET (see Column 6, Lines 3-6). PET is a well-known polyethylene.

15. Regarding claim 38, the sheath has a length substantially less than the length of the catheter (see Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. **Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 1 above, and further in view of Wilson et al. (6,165,195).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). However, Stone et al. reference does not disclose a guidewire assembly. Attention is drawn to Wilson et al. reference, which teaches a guidewire housing included in the catheter assembly (see Figures 12D-12F) to assist in proper placement of the stent with respect to a branch vessel. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to attached the guidewire housing of Wilson et al. reference to the sheath of Stone et al. reference to assist in proper placement of the stent with respect to a branch vessel.

17. Regarding claims 2-3, Stone et al. reference discloses a stent (28) disposed about the sheath and Wilson et al. reference shows the stent lying partially about the guidewire housing (see Figure 12F).

18. **Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 6 above, and further in view of Bigus et al. (Patent Application Publication 2002/0052640).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). However, Stone et al. reference does not disclose the first and third portions are tapered and the third portion having a smaller inner diameter than the

second portion. Attention is drawn to Bigus et al. reference, which teaches different portions of a sheath may have varying thicknesses (see Figure 7), and accordingly will have varying diameters to control expansion characteristics of the balloon that lies beneath the sheath. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the sheath of Stone et al. reference with varying thickness in the manner taught by Bigus et al. reference to control expansion characteristics of the balloon that lies beneath the sheath.

19. Regarding claims 7-9, the first and third portions of the sheath of Bigus et al. reference are considered to be the end portions 56a-b and 56d-e, respectively. The second portion is interpreted to be section 56c. Although Bigus et al. reference shows the sheath with a constant inner diameter in figure 7, paragraph 49 discloses the sheath simply has varying thickness along its length, and therefore could have a constant outer diameter and the inner diameter varied. With this configuration, the first and third portions would have a smaller inner diameter than the second portion. Bigus et al. reference also discloses the sheath gets progressively thinner towards its center (see paragraph 49) and therefore is interpreted as being tapered.

20. **Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 15 above, and further in view of Bigus et al. (Patent Application Publication 2002/0052640).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). However, Stone et al. reference does not disclose

the outer diameters of the end portions of the sheath are equal or greater to the outside diameter of the stent. Attention is drawn to Bigus et al. reference, which teaches different portions of a sheath may have varying thicknesses (see Figure 7), to control expansion characteristics of a balloon and allow a stent to be nested about the sheath while preventing it from snagging on a wall of a vessel during implantation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to thicken the outer portions of the sheath to allow the stent to be nested about the sheath while preventing it from snagging on a wall of a vessel during implantation.

21. Regarding claims 21-23, the outer diameters of the sheath of Bigus et al. reference are capable of being "at least as great as," "substantially equal to," or "substantially greater than" the outer diameter of the stent, depending on the magnitude of the increase in wall thickness of the sheath.

22. **Claims 24-26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 15 above, and further in view of Healy et al. (5,670,161).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). However, Stone et al. reference does not disclose a portion of the stent is coated with a therapeutic agent. Attention is drawn to Healy et al. reference, which teaches a stent may be coated with a therapeutic agent to positively affect healing at the site where the stent is deployed (see Column 10, Lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to coat the stent of Stone et al. reference with a therapeutic agent, as taught by Healy et al. reference, to positively affect healing at the site where the stent is deployed.

23. Regarding claim 25, the therapeutic agent may include heparin (see Column 10, Line 22).

24. Regarding claim 26, the therapeutic agent may include growth factors (see Column 10, Line 16).

25. Regarding claim 29, the therapeutic agent may include polyvinylpyrrolidone (see Column 10, Lines 36-37).

26. **Claims 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) in view of Healy et al. (5,670,161) as applied to claim 24 above, and further in view of Clapper (5,744,515).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). The combination of Stone et al. and Healy et al. references teaches the stent may be coated with a therapeutic agent. However, the combination of Stone et al. and Healy et al. references does not teach the therapeutic agent is a cellular material. Attention is drawn to Clapper reference, which teaches a cellular material (for example, a vascular graft) used on an implantable device (see Column 7, Lines 31-33 and 46-52) to provide a more compliant implant with a reduced risk of rejection by the body of the patient upon its implantation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made

to coat the stent of Stone et al. reference with a tissue engineering graft, as taught by Clapper reference, to provide a more compliant implant with a reduced risk of rejection by the body of the patient upon its implantation.

27. **Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 1 above, and further in view of Lenker et al. (6,350,278).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). However, Stone et al. reference does not disclose a lubricious coating positioned between the sheath and the shaft. Attention is drawn to Lenker et al. reference, which teaches a lubricious material be applied between the catheter shaft and the sheath (see Column 9, Lines 58-64) to reduce the amount of friction between the two components. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include a lubricous coating between the sheath and the catheter shaft, as taught by Lenker et al. reference, in the device of Stone et al. reference to reduce the amount of friction between the two components.

28. **Claim 31, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 1 above, and further in view of Noveon (www.estane.com).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon (24), and a rotatable sheath (40) with a first portion (44) and second portion (42). However, Stone et al. reference does not disclose that the sheath is made

at least partially of a hydrophilic polymer. Attention is drawn to the Noveon website, which teaches that a Tecophillic TPU (thermoplastic polyurethane) is hydrophilic (see excerpt below from the website) to absorb water and decrease the amount of dry friction between the sheath and the catheter shaft. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the Stone et al. sheath with Tecophilic TPU which is a hydrophilic material (as taught by Noveon) to absorb water and decrease the amount of dry friction between the sheath and the catheter shaft.

> **Major Benefits of Tecophilic® TPUs:**
> ***Tecophilic ((hydrophilic, aliphatic, polyether-based TPU), Shore A 90 through Shore D 60***
> A family of aliphatic, polyether-based TPUs which have been specially formulated to absorb equilibrium water contents of up to 150% of the weight of dry resin. Extrusion grade formulations are designed to provide maximum physical properties of thermoformed tubing or other components. Solution grade formulations are designed to provide greater solubility in organic solvents to prepare lacquers for coating applications. This technology has been expanded to a **Tecophilic® Gel.** It is a hydrogel that can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of dry resin. The materials were designed as a coating cast from an ethanol/water solvent system. Other solvent systems such as THF/water and DMAC can be used. Tecophilic Gel is melt processible using modified injectin molding and extrusion methods.

29. Regarding claim 32, Tecophilic is a registered trademark and is a hydrophilic material, and therefore the rejection of claim 31 also applies to claim 32.

30. Regarding claim 34, Tecophilic is a hydrophilic polyurethane (see excerpt above).

31. **Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (5,843,027) as applied to claim 35 above, and further in view of Noveon (www.estane.com).** Stone et al. reference discloses the catheter assembly substantially as claimed, including a catheter (10) having a catheter shaft (12), a balloon

(24), and a rotatable sheath (40) with a first portion (44) and second portion (42). Stone et al. reference also discloses a first material is a polymer matrix and a second material is a reinforcing material. However, Stone et al. reference does not disclose the polymer matrix is a hydrophilic polyurethane. Attention is drawn to the Noveon website, which teaches that a Tecophillic TPU (thermoplastic polyurethane) is hydrophilic to absorb water and decrease the amount of dry friction between the sheath and the lumen it is inserted into. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the polymer matrix (outer layer) Stone et al. sheath with Tecophilic TPU which is a hydrophilic material (as taught by Noveon) to absorb water and decrease the amount of dry friction between the sheath and the lumen it is inserted into.

Conclusion

32. The prior art made of record and not relied upon and is considered pertinent to applicant's disclosure is as follows: 5,749,825 to Fischell et al. and 6,048,350 to Vrba.

33. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ryan Severson whose telephone number is (571) 272-3142. The examiner can normally be reached on Monday - Thursday 7:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

34. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ryan Severson
November 28, 2006

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
12/5/06